

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No. : 10/524,334  
Applicant : OSHLACK et al.  
Filed: February 11, 2005  
Art Unit : 1615  
Examiner : Hasan Syed Ahmed  
Docket No. : 200.1156US  
Customer No. : 23280  
For : **PHARMACEUTICAL COMPOSITIONS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA, 22313-1450

March 25, 2010

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with Applicants' duty of disclosure under 37 C.F.R. § 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (1 page) for consideration by the Examiner in connection with the examination of the above-identified patent application.

Applicants note that documents A05 to A10 and A13 were cited in an Office Action issued in connection with Japanese Patent Application No. 2005-504461 on February 2, 2010. A copy of the Japanese Office Action, along with the English translation thereof, is attached as Appendix A.

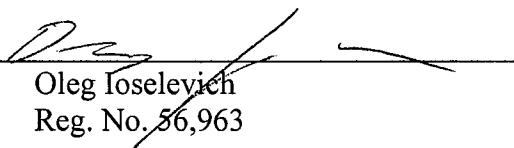
Applicants further note that document A13 (WO 01/058447) was previously brought to the Examiner's attention in the Information Disclosure Statement filed on March 21, 2006.

In accordance with 37 C.F.R. § 1.98 (a)(2), copies of the documents listed in the FOREIGN PATENT DOCUMENTS and OTHER REFERENCES sections of the accompanying Form PTO-1449 are enclosed.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(c), "before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application" and is accompanied by a check to cover the fee set forth in § 1.17(p). In the event any additional fee is due or an overpayment has been made in connection with the filing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge said fee or credit said overpayment to our Deposit Account No. 50-0552.

Respectfully submitted,  
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## **APPENDIX A**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /HA

**NOTICE OF REASONS FOR REJECTION**

Patent Application No.: 2005-504461  
Drafting Date: January 28, 2010  
Patent Examiner: Naoto Iwashita  
Attorney for Applicant: Hiroshi Kobayashi, et al.  
Provisions Applied: Article 29, Para. 2; Article 36

This application should be rejected for the following reasons. If the applicant has any arguments, a response can be filed within three months of the mailing date of this notice.

**Reasons**

1. The invention of this patent application could have been easily made by one of ordinary skill in the art based on the inventions described in the following publications distributed prior to the filing date in Japan or abroad. Thus, this patent application should be rejected under Article 29, Para. 2 (obviousness).

2. This application does not satisfy the requirement under Article 36, Para. 6, Subpara. 2 (indefinite) for the reasons described below.

3. This application does not satisfy the requirement under Article 36, Para. 4, Subpara. 1 (enablement) for the reasons described below.

**Remarks****List of Cited References**

1. WO01/059447
2. Japanese national phase translation of PCT No. 2001-505897
3. WO00/35426
4. Japanese national phase translation of PCT No. H09-505602
5. Japanese Publication Laid-open No. H07-145056
6. WO01/068058
7. Japanese Publication Laid-open No. H07-002650

**Reason 1**

-Claims 1-21

-Cited References 1-7

-Notes

Cited References 1 and 2 describe a controlled-release formulation comprising an opioid antagonist. As described in Cited References 1 and 3-7, it is interpreted

polymer, hydrophobic material or the like, and providing multiple-layer coating at that time can be suitably practiced by those skilled in the art. Therefore, when obtaining a controlled-release formulation comprising an opioid antagonist, providing coating using an acrylic polymer, enteric polymer, hydrophobic material, etc. in suitable combination can be easily practiced by those skilled in the art.

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It is not interpreted that the inventions defined by the above-described claims exert significantly meritorious effects beyond the prediction of those skilled in the art.

### Reason 2

- (1) Due to the word "about" recited in claim 10, the invention is not clear.
- (2) Claim 15 recites "provides for the sequestration". The meaning of the recitation is not clear.
- (3) Claims 1 and 18 recite "a diffusion barrier coating comprising an anionic polymer coated over said substrate" and "a coating comprising a hydrophobic material coated over said diffusion barrier coating". It is not clear what kind of compound each of the coatings specifically consists of. Moreover, in view of the descriptions in paragraphs [0026] to [0043] (*AIK note: [0026] to [0043] of the WO publication*), specific compounds which can constitute one of the coatings overlap those which can constitute the other coating. It is not clear what kind of difference exists between these "coatings". Further, it is not clear what kind of function and characteristics are possessed by each of the coatings.

Accordingly, the inventions defined by the above-described claims and other claims which are dependent from the above-described claims are not clear.

### Reason 3

Though Examples 6 and 8 in the present specification do not have "a diffusion barrier coating comprising an anionic polymer", they are described as "Examples".

The present specification does not describe the inventions according to the claims in such a clear and sufficient manner so as to enable those skilled in the art to practice the inventions.

End of text

整理番号: \_\_\_\_\_ 発送番号: 068276 発送日: 平成22年 2月 2日 \_\_\_\_\_ 1

**拒絶理由通知書  
(Office Action)**

特許出願の番号	特願 2005-504461
起案日	平成22年 1月28日
特許庁審査官	岩下 直人 9841 4C00
特許出願人代理人	小林 浩 (外 3名) 様
適用条文	第29条第2項、第36条

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から3か月以内に意見書を提出してください。

**理 由**

理由1 この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記Aの刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第29条第2項の規定により特許を受けることができない。

理由2 この出願は、特許請求の範囲の記載が下記の点で、特許法第36条第6項第2号に規定する要件を満たしていない。

理由3 この出願は、発明の詳細な説明の記載が下記の点で、特許法第36条第4項第1号に規定する要件を満たしていない。

記 (引用文献等についてはAを参照)

A

1. 国際公開第01/058447号
2. 特表2001-505897号公報
3. 国際公開第00/35426号
4. 特表平09-505602号公報
5. 特開平07-145056号公報
6. 国際公開第01/068058号
7. 特開平07-002650号公報

理由 1

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整理番号: 発送番号:068276 発送日:平成22年 2月 2日 2

- ・請求項 1-21
- ・引用文献等 A1-A7
- ・備考

A1-A2には、オピオイドアンタゴニストを含む制御放出製剤が記載されている。A1, A3-A7に記載されるように、アクリルポリマーや腸溶性ポリマー、疎水性材料等によりコーティングを行うことで薬物の放出制御を行うこと、また、その際複数層のコーティングを行うことは当業者が適宜なし得るものと解されるので、オピオイドアンタゴニストを含む制御放出製剤を得る場合において、アクリルポリマーや腸溶性ポリマー、疎水性材料等を適宜組み合わせてコーティングをおこなってみるとは当業者が容易になし得るものである。

請求項に係る発明とすることにより当業者の予測を超えるような格別に顕著な効果を生じるものとも解されない。

### 理由2

- (1) 請求項10の「約」なる記載は発明を不明確とするものである。
- (2) 請求項15の「隔壁をもたらす」の意味するところが不明である。
- (3) 請求項1, 18の「前記基質を被覆するアニオン性ポリマーを含む拡散バリアコーティング」および「前記拡散バリアコーティングを被覆する疎水性材料を含むコーティング」がそれぞれ具体的に如何なる化合物よりなるものであるのか不明である。また、第【0026】段落～第【0043】段落の記載によれば、両「コーティング」を構成し得る具体的な化合物は重複しており、両「コーティング」が互いに如何に相違し、それぞれ如何なる機能・性質を備えるものであるのか判然としない。

以上の請求項およびこれらを引用する他の請求項に係る発明は明確でない。

### 理由3

本願明細書実施例6, 実施例8は、「アニオン性ポリマーを含む拡散バリアコーティング」を有さないにもかかわらず「実施例」と記載されている。

この出願の発明の詳細な説明は、当業者が請求項に係る発明を実施することができる程度に明確かつ十分に記載されたものでない。

#### 先行技術文献調査結果の記録

・調査した分野 I P C A61K31/00, 47/00, A61P25/00

D B名

・先行技術文献

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

この拒絶理由通知に関するお問い合わせがございましたら下記までご連絡下さい。

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /HA/

整理番号: 発送番号:068276 発送日:平成22年 2月 2日 3/E

特許審査第三部 医療 岩下直人  
TEL. 03(3581)1101 内線3451

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. <b>200.1156</b>	APPLICATION NO <b>10/524,334</b>
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)		APPLICANT <b>Benjamin OSHLACK et al.</b>			
		FILING DATE <b>February 11, 2005</b>	GROUP <b>1615</b>		

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A01	6,419,959	07/16/2002	Kersten WALTER et al.			
	A02	5,958,459	09/28/1999	Mark CHASIN et al.			
	A03	2002/0192282	10/14/2003	Thomas BECKERT et al.			
	A04						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	YES	NO
							See document A01		
	A05	2001-505897	08/05/2001	JP					
	A06	WO 00/035426	06/22/2000	PCT					
	A07	H09-505602	03/06/1997	JP			See document A11		
	A08	H07-145056	06/06/1995	JP			See document A02		
	A09	WO 01/068058	09/20/2001	PCT			See English abstract and Document A03		
	A10	H07-02650	06/01/1995	JP			See document A12		
	A11	WO 95/014460	06/01/1995	PCT					
	A12	EP 0629398	12/21/1994	EP					
	A13	WO 01/058447	08/16/2001	PCT					

**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)**

A14	
A15	
A16	
A17	
A18	
A19	
A20	
A21	
A22	
A23	
A24	
A25	

EXAMINER /Hasan Ahmed/  
**Hasan S.  
Ahmed**

DATE CONSIDERED 03/28/2010

Digitally signed by Hasan S. Ahmed  
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Person: I have reviewed this  
document.  
Date: 2010.03.28 11.03.37 -0400

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /HA/